

IN THE CLAIMS:

1. (WITHDRAWN) A therapeutic agent delivery implant for implantation into a patient's body, said implant comprising:

a resilient or flexible, at least partially hydrophobic reticulated elastomeric support scaffold and

one or more therapeutic agents secured to and/or supported by the scaffold for release within the patient.

2. (CURRENTLY AMENDED) A therapeutic agent delivery implant for implantation into a patient's body, said implant consisting essentially of:

a resilient or flexible, at least partially hydrophobic reticulated elastomeric support foam matrix scaffold; and

a hydrophilic coating arranged on said scaffold,

wherein said coating contains one or more therapeutic agents for release within the patient.

3. (CURRENTLY AMENDED) The implant of Claim 2, wherein the scaffold comprises at least one therapeutic agent ~~is secured to and/or supported by the scaffold.~~

4. (CURRENTLY AMENDED) The implant of Claim ~~4~~ or 2, wherein at least one therapeutic agent is contained within microspheres in the coating.

5. (CURRENTLY AMENDED) The implant of Claim ~~4~~ or 2, wherein the scaffold is biodurable.

6. (ORIGINAL) The implant of Claim 2, wherein at least one therapeutic agent is contained within microspheres in the coating.

7. (ORIGINAL) The implant of Claim 2, wherein the coating contains enzymes.

8. (CURRENTLY AMENDED) The implant of Claim ~~4~~ 2, wherein the ~~[[the]]~~ scaffold comprises a hydrophobic polyurethane.

9. (ORIGINAL) The implant of Claim 2, wherein the coating comprises a hydrophilic polyurethane.

10. (CURRENTLY AMENDED) The implant of Claim ~~4~~ 2, wherein the therapeutic agent is selected from the group consisting of a pharmaceutical, a growth factor, an enzyme, RNA, DNA, a nucleic acid, and a vector, and mixtures of two or more thereof.

11. (CURRENTLY AMENDED) The implant of Claim ~~4~~ 2 which has a hemispherical, bullet, football, cylindrical, spherical, or irregular shape.

12. (ORIGINAL) The implant of Claim 11 which is spaghetti-shaped.

13. (WITHDRAWN) A method of delivering an implant to a mammalian site, which comprises the steps of:

- (a) collapsing and/or compressing an implant of Claim 1 or 2;
- (b) inserting the implant from step (a) into a rigid or flexible delivery instrument having a distal tip;
- (c) advancing the delivery instrument distal tip to a desired site;
- (d) deploying the implant at the desired site, whereby the implant expands to a size and shape substantially similar to its size and shape before step (a); and
- (e) withdrawing the delivery instrument.

14. (WITHDRAWN) The method of Claim 13, wherein the delivery instrument is a cannular, trocar, catheter, or a minimally invasive rigid or flexible instrument.

15. (WITHDRAWN) The method of Claim 14, wherein the minimally invasive instrument incorporates visualization or electromechanics.

16. (WITHDRAWN) The method of Claim 15, wherein the minimally invasive instrument has a fiberoptic guide.

17. (WITHDRAWN) The method of Claim 14, wherein the minimally invasive instrument is a cystoscope, laproscope, arthroscope, or endoscope.

18. (WITHDRAWN) The method of Claim 13, wherein the desired delivery site is the patient's bladder and the delivery instrument is advanced through the patient's urethra.

19. (WITHDRAWN) A method of treating a patient, which comprises the steps of:

- (a) collapsing and/or compressing an implant of Claim 1 or 2;
- (b) inserting the implant from step (a) into a rigid or flexible delivery instrument having a distal tip;
- (c) advancing the delivery instrument distal tip to a desired site;
- (d) deploying the implant at the desired site whereby the implant expands to a size and shape substantially similar to its size and shape before step (a);
- (e) withdrawing the delivery instrument; and
- (f) leaving the implant in place for a desired period of time.

20. (WITHDRAWN) The method of Claim 19, which also comprises the steps of:

- (g) advancing the distal tip of a removal instrument to the desired site;
- (h) engaging the implant; and
- (i) withdrawing the implant and the removal instrument from the patient.

21. (WITHDRAWN) The method of Claim 19, wherein the delivery instrument is a cannular, trocar, catheter, or a minimally invasive rigid or flexible instrument.

22. (WITHDRAWN) The method of Claim 21, wherein the minimally invasive instrument incorporates visualization or electromechanics.

23. (WITHDRAWN) The method of Claim 22, wherein the minimally invasive instrument has a fiberoptic guide.

24. (WITHDRAWN) The method of Claim 21, wherein the minimally invasive instrument is a cystoscope, laproscope, arthroscope, or endoscope.

25. (WITHDRAWN) The method of Claim 20, wherein the removal instrument is a cannular, trocar, catheter, or a minimally invasive rigid or flexible instrument.

26. (WITHDRAWN) The method of Claim 25, wherein the minimally invasive instrument incorporates visualization or electromechanics.

27. (WITHDRAWN) The method of Claim 26, wherein the minimally invasive instrument has a fiberoptic guide.

28. (WITHDRAWN) The method of Claim 25, wherein the minimally invasive instrument is a cystoscope, laproscope, arthroscope, or endoscope.

29. (WITHDRAWN) A method of systemically or locally treating a patient, which comprises the steps of:

- (a) positioning an implant of Claim 1 or 2 at a desired site within a patient; and
- (b) leaving the implant at the desired site for a suitable period of time.

30. (WITHDRAWN) A system for treating a patient, which comprises an implant of Claim 1 or 2 and a delivery instrument.

31. (WITHDRAWN) The system of Claim 30, wherein the delivery instrument is a cannular, trocar, catheter, or a minimally invasive rigid or flexible instrument.

32. (WITHDRAWN) The system of Claim 31, wherein the minimally invasive instrument incorporates visualization or electromechanics.

33. (WITHDRAWN) The system of Claim 32, wherein the minimally invasive instrument has a fiberoptic guide.

34. (WITHDRAWN) The system of Claim 31, wherein the minimally invasive instrument is a cystoscope, laproscope, arthroscope, or endoscope.

35. (WITHDRAWN) The system of Claim 30 which also comprises a removal instrument.

36. (WITHDRAWN) The system of Claim 35, wherein the removal instrument is a cannular, trocar, catheter, or a minimally invasive rigid or flexible instrument.

37. (WITHDRAWN) The system of Claim 36, wherein the minimally invasive instrument incorporates visualization or electromechanics.

38. (WITHDRAWN) The system of Claim 37, wherein the minimally invasive instrument has a fiberoptic guide.

39. (WITHDRAWN) The method of Claim 36, wherein the minimally invasive instrument is a cystoscope, laproscope, arthroscope, or endoscope.

40. (WITHDRAWN) A method of treating a local urological condition in a patient, which comprises the steps of:

- (a) collapsing and/or compressing an implant of Claim 1 or 2;
- (b) inserting the implant from step (a) into a rigid or flexible delivery instrument having a distal tip;
- (c) advancing the delivery instrument distal tip through the patient's urethra to the bladder;
- (d) deploying the implant in the bladder whereby the implant expands to a size and shape substantially similar to its size and shape before step (a);
- (e) withdrawing the delivery instrument; and
- (f) leaving the implant in place in the bladder for a desired period of time.

41. (WITHDRAWN) The method of Claim 40, wherein the local condition to be treated is cancer, an infection, an inflammation, a neurological condition, or a trauma,

42. (WITHDRAWN) A method of treating a condition in a patient that is systemic or external to the bladder, which comprises the steps of:

- (a) collapsing and/or compressing an implant of Claim 1 or 2, wherein the implant or the coating thereon comprises a solubilizer;
- (b) inserting the implant from step (a) into a rigid or flexible delivery instrument having a distal tip;

(c) advancing the delivery instrument distal tip through the patient's urethra to the bladder;

(d) deploying the implant in the bladder whereby the implant expands to a size and shape substantially similar to its size and shape before step (a); (e) withdrawing the delivery instrument; and

(e) leaving the implant in place in the bladder for a desired period of time.

43. (WITHDRAWN) The method of Claim 42, wherein the condition to be treated is cancer, an infection, an inflammation, a neurological condition, or osteomyelitis.

44. (WITHDRAWN AND CURRENTLY AMENDED) A therapeutic agent delivery implant for implantation to a mammalian site, the implant comprising:
a resilient or flexible, hydrophobic support reticulated elastomeric scaffold
and

at least one therapeutic agent secured to ~~and~~ and/or supported by the scaffold for release at the mammalian site,

wherein the therapeutic agent delivery implant is insertable into a mammalian bladder or other suitable site via the urethra and is locatable within the bladder.

45. (WITHDRAWN) The implant of Claim 44, wherein the implant is capable of being kept out of stimulative contact with the trigone during the normal daily host routine.

46. (WITHDRAWN) The implant of Claim 44, wherein the therapeutic agent delivery implant remains stable and fixed against the mucous membrane of the bladder away from the trigone.

47. (WITHDRAWN) The implant of Claim 44, wherein the therapeutic agent delivery implant is locatable in the dome of the bladder and permits flow of urine through the therapeutic agent delivery implant material.

48. (WITHDRAWN) The implant of Claim 44, wherein the therapeutic agent delivery implant is shaped to engage and lodge against the bladder inner wall.

49. (WITHDRAWN) The implant of Claim 44, wherein the therapeutic agent delivery implant is configured, sized and prestressed to have a cross-sectional area in excess of the anticipated maximum cross-sectional area of the intended recipient bladder.

50. (WITHDRAWN) The implant of Claim 44, wherein the therapeutic agent delivery implant is elastically compressible.

51. (WITHDRAWN) A method of delivering an implant to a mammalian site comprising the steps of:

- (a) collapsing and/or loading into a delivery instrument a resiliently compressible therapeutic agent delivery implant having an expanded configuration when deployed;

- (b) advancing the delivery instrument through a mammalian urethra to access the bladder;

- (c) deploying the therapeutic agent delivery implant through the delivery instrument into the bladder; and

- (d) withdrawing the delivery instrument, leaving the therapeutic agent delivery implant in the bladder.

52. (WITHDRAWN) The method of Claim 51, wherein the therapeutic agent delivery implant can be pulled into a removal instrument, insertable into the urethra, and the method further comprising the steps of:

- (e) advancing the removal instrument into the urethra and

(f) removing the therapeutic agent delivery implant from the bladder with the removal instrument.

53. (WITHDRAWN) The method of Claim 51 or 52, wherein the delivery instrument and the removal instrument are each a cannular, trocar, catheter, or a minimally invasive rigid or flexible instrument.

54. (WITHDRAWN) The method of Claim 53, wherein the minimally invasive instrument incorporates visualization or electromechanics.

55. (WITHDRAWN) The method of Claim 54, wherein the minimally invasive instrument has a fiberoptic guide.

56. (WITHDRAWN) The method of Claim 53, wherein the minimally invasive instrument is a cystoscope, laproscope, arthroscope, or endoscope.

57. (WITHDRAWN) The method of Claim 52, wherein a gripping implement, deployed through the removal instrument grips the therapeutic agent delivery implant and draws it into the removal instrument.

58. (WITHDRAWN) The method of Claim 57, wherein the gripping implement comprises a forceps or hook.

59. (WITHDRAWN) The method of Claim 52, wherein removal is effected within from one to twenty-eight days after insertion.

60. (CANCELLED)

61. (CURRENTLY AMENDED) The implant of Claim 1-~~or~~ 2, wherein the scaffold comprises a biodegradable, resilient, compressible, elastomeric reticulated matrix.

62. (CANCELLED)

63. (CURRENTLY AMENDED) The implant of Claim ~~4~~ 2, wherein the scaffold can be compressed during delivery and can recover to a working size and configuration *in situ* at the implantation site.

64. (CURRENTLY AMENDED) The implant of Claim 9 which after recovery to a working size and configuration is similar to ~~the original~~ a size and shape before compression.

65. (CURRENTLY AMENDED) The implant of Claim 9 which can be retrieved and withdrawn from the patient's body.

66. (CURRENTLY AMENDED) The reticulated implant of Claim ~~4~~ 2 ~~[[,]]~~ which allows for substantial fluid permeability, good flow through characteristics and access for body fluid to the drug bearing surfaces.

67. (CURRENTLY AMENDED) The reticulated implant of Claim ~~4~~ 2 which facilitates transport of therapeutic agent or that is secured to and/or supported by the scaffold.

68. (PREVIOUSLY PRESENTED) The implant of claim 2, wherein the scaffold material is selected from the group consisting of polycarbonate polyurethane.

69. (PREVIOUSLY PRESENTED) The implant of claim 2, wherein the scaffold material is selected from the group consisting of polycarbonate polyurethane, or polycarbonate-polysiloxane polyurethanes, polysiloxane polyurethanes, polycarbonate-hydrocarbon polyurethanes, polycarbonate-hydrocarbon polyurethane-ureas, and mixtures of two or more thereof.

70 - 71. (CANCELLED)

72. (PREVIOUSLY PRESENTED) The implant of Claim 2, wherein the coating comprises a foam.

73. (PREVIOUSLY PRESENTED) The implant of Claim 2, wherein the coating comprises a film.

74. (PREVIOUSLY PRESENTED) The implant of Claim 2, wherein the coating comprises a hydrogel.

75. (PREVIOUSLY PRESENTED) The implant of Claim 2, wherein the coating comprises a biodegradable polymer.

76. (PREVIOUSLY PRESENTED) The implant of Claim 2, wherein the coating comprises a non-biodegradable polymer.

77. (CANCELLED)

78. (CURRENTLY AMENDED) The implant of Claim 2, wherein the scaffold is formed from a polyurethane pre-polymer.

79. (NEW) The implant of Claim 2, wherein the foam matrix scaffold comprises interconnected pores and the average diameter or other largest transverse dimension of the pores is from about 50 μm to about 2000 μm .

80. (NEW) The implant of Claim 79, wherein the average diameter or other largest transverse dimension of the pores is from about 50 μm to about 800 μm .

81. (NEW) The implant of Claim 80, wherein the average diameter or other largest transverse dimension of the pores is from about 100 μm to about 500 μm .

82. (NEW) The implant of Claim 2, wherein the void phase of the foam matrix scaffold is at least 50% by volume of the volume of the scaffold.

83. (NEW) The implant of Claim 81, wherein the void phase of the foam matrix scaffold is from about 70% to about 99% of the volume of the scaffold.